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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,652	11/25/2003	Glenn R. Gibson	N-32809A	7110

1095 7590 01/31/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
VANIK, DAVID L	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,652	GIBSON ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *12-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/12/05, 6/18/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Applicant's response to the Election/Restriction requirement filed on 12/12/2005.

Election/Restrictions

Applicant's election of Claims 1-11 in the reply filed on 12/12/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 8, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Moro et al ("Dosage-Related Bifidogenic Effects of Galacto- and Fructooligosaccharides in Formula-Fed Term Infants").

Moro et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See pages 291, 294 and Table 1). According to Moro et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page 292). This satisfies the weight ratio of FOS:GOS of about 0.01 to about 50. According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation. As formulated, it is the examiner's position that the formula advanced by Moro et al. is both "nutritionally complete" and "ready-for-consumption."

The claims are therefore anticipated by Moro et al ("Dosage-Related Bifidogenic Effects of Galacto- and Fructooligosaccharides in Formula-Fed Term Infants").

Claims 1, 3, 5, 8, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehm et al ("Supplementation of a bovine milk formula with an oligosaccharide mixture increases counts of faecal bifidobacteria in preterm infants").

Boehm et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See page F179 and Table 1). According to Boehm et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page F178). According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation. As formulated, it is the examiner's position that the

formula advanced by Boehm et al. is both "nutritionally complete" and "ready-for-consumption."

The claims are therefore anticipated by Boehm et al ("Supplementation of a bovine milk formula with an oligosaccharide mixture increases counts of faecal bifidobacteria in preterm infants").

Claims 1, 5, 7-8, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Rigo et al ("Growth, weight gain composition and mineral accretion in term infants fed a new experimental formula containing hydrolyses protein, palmitate and prebiotics").

Rigo et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See Table 1). According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation, and over 1% of protein can be present per 100 kcal. As formulated, it is the examiner's position that the formula advanced by Rigo et al. is both "nutritionally complete" and "ready-for-consumption."

The claims are therefore anticipated by Rigo et al ("Growth, weight gain composition and mineral accretion in term infants fed a new experimental formula containing hydrolyses protein, palmitate and prebiotics").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 6, 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al ("Dosage-Related Bifidogenic Effects of Galacto- and Fructooligosaccharides in Formula-Fed Term Infants").

The teachings of Moro et al. are discussed above. Moro et al. is deficient in the sense that it does not teach the exact percentage of ingredients and ratio of GOS to FOS.

As set forth above, Moro et al. teach a baby formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See pages 291, 294 and Table 1). Because the exact formulation and portion of a baby

formula is determined on the basis of age, size, and sex of an infant, one of ordinary skill in the art would have the ability to optimize the infant formula advanced by Moro et al. There is a reasonable expectation that optimizing a infant formula on the basis of sex, age, and size of the infant would result in a formula capable of delivering the appropriate amount of nutrients to said infant. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition advanced by Moro et al. on the basis of the age, sex, and size of the infant.

Claims 4, 6, 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehm et al ("Supplementation of a bovine milk formula with an oligosaccharide mixture increases counts of faecal bifidobacteria in preterm infants").

The teachings of Boehm et al. are discussed above. Boehm et al. is deficient in the sense that it does not teach the exact percentage of ingredients and ratio of GOS to FOS.

As set forth above, Boehm et al. teach a baby formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See Table 1). Because the exact formulation and portion of a baby formula is determined on the basis of age, size, and sex of an infant, one of ordinary skill in the art would have the ability to optimize the infant formula advanced by Boehm et al. There is a reasonable expectation that optimizing a infant formula on the basis of sex, age, and

size of the infant would result in a formula capable of delivering the appropriate amount of nutrients to said infant. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition advanced by Boehm et al. on the basis of the age, sex, and size of the infant.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al ("Dosage-Related Bifidogenic Effects of Galacto- and Fructooligosaccharides in Formula-Fed Term Infants") in view of US 5,827,526 ('526).

The teachings of Moro et al. are discussed above. Although Moro et al. teaches the benefits of an infant formula comprising a combination of GOS and FOS, Moro et al. does not specifically teach an infant formula comprising GOS and FOS wherein FOS and GOS have a degree of polymerization ranging from about 2 to 7.

Like Moro et al., '526 teach infant formulas. Additionally, '526 teach the incorporation of GOS and FOS into infant formula to treat the occurrence of diarrhea (See abstract and column 3, lines 35-47). According to '526, it is advantageous to formulate the infant formula with GOS and/or FOS having a degree of polymerization of between 2-20 (column 7, lines 42-49). Preferably, according to '526, the FOS is either 1-ketose or nytose (column 3, lines 41-47). Because GOS and FOS having a degree of polymerization between 2-20 can advantageously treat the occurrence of diarrhea in infants, one of ordinary skill in the art would have been motivated use GOS and FOS

having a degree of polymerization between 2-20 in the infant formula advanced by Moro et al. Based on the teachings of '526, there is a reasonable expectation that the use of GOS and FOS having a degree of polymerization between 2-20 in an infant formula would effectively treat the occurrence of diarrhea. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use GOS and FOS having a degree of polymerization between 2-20 in the invention advanced by Moro et al. in view of the teachings of '526.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehm et al ("Supplementation of a bovine milk formula with an oligosaccharide mixture increases counts of faecal bifidobacteria in preterm infants") in view of US 5,827,526 ('526).

The teachings of Boehm et al. are discussed above. Although Boehm et al. teaches the benefits of an infant formula comprising a combination of GOS and FOS, Boehm et al. does not specifically teach an infant formula comprising GOS and FOS wherein FOS and GOS have a degree of polymerization ranging from about 2 to 7.

Like Boehm et al., '526 teach infant formulas. Additionally, '526 teach the incorporation of GOS and FOS into infant formula to treat the occurrence of diarrhea (See abstract and column 3, lines 35-47). According to '526, it is advantageous to formulate the infant formula with GOS and/or FOS having a degree of polymerization of between 2-20 (column 7, lines 42-49). Preferably, according to '526, the FOS is either

1-ketose or nytose (column 3, lines 41-47). Because GOS and FOS having a degree of polymerization between 2-20 can advantageously treat the occurrence of diarrhea in infants, one of ordinary skill in the art would have been motivated use GOS and FOS having a degree of polymerization between 2-20 in the infant formula advanced by Boehm et al. Based on the teachings of '526, there is a reasonable expectation that the use of GOS and FOS having a degree of polymerization between 2-20 in an infant formula would effectively treat the occurrence of diarrhea. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use GOS and FOS having a degree of polymerization between 2-20 in the invention advanced by Boehm et al. in view of the teachings of '526.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1615

1/27/06

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